

FEB - 4 1997

**510(K) SUMMARY**

---

The FemRx <sup>TURP</sup>SR™ System is intended for urological transurethral resection by trained professional urologists in hospital environments. This device is intended for resection of tissue in the urethra, prostate and bladder.

The FemRx <sup>TURP</sup>SR™ System is a refined urologic resectoscope. A standard telescope is inserted into the device and coupled to an operative video camera system prior to use. The device is compatible with a variety of standard electro-surgery units (ESUs).

The system is designed to cut and coagulate prostate tissue by sliding the loop assembly in an axial manner relative to the handle/spring housing. Cutting and coagulation are accomplished by energizing the electrode with electrocautery current from an approved ESU. All cutting/coagulating occurs under visual control by a surgeon observing a video monitor displaying the view through the telescope. Cutting/coagulating is only performed while the device is moving *towards* the operator. Typically, the surgeon squeezes the finger rings to move cutting end distally; electrocautery is then applied and cutting/coagulating is accomplished by the active end as the spring returns the device to the most proximal resting location. The surgeon uses hand pressure to control the rate of sliding of the active end within the sheath. Separate channels are provided for irrigant inflow and outflow, permitting continuous fluid circulation for good visibility.

The system as described in the preceeding 3 paragraphs is identical (substantially equivalent) in all design and component aspects, except one, to the FemRx <sup>TURP</sup>STAR™ System which is also used in urological applications. The <sup>TURP</sup>STAR™ system has an additional component, a morcellator, which uses an arthroscopic shaver to reduce the size of the resected tissue prior to the tissue being carried out the fluid path. Neither of the other referenced predicate devices (the Circon/ACMI USA Elite™ and the Olympus A2757 Resectoscope) nor the <sup>TURP</sup>SR™ have a morcellator.